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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**on the status of certain products as feed additives within the scope of Regulation (EC)
No 1831/2003 of the European Parliament and of the Council and on the withdrawal
from the market of certain feed additives**

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

on the status of certain products as feed additives within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council and on the withdrawal from the market of certain feed additives

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition¹, and in particular Articles 2(3) and 10(5) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. In particular, Article 10(2), in conjunction with Article 10(7) of that Regulation provides for specific procedures for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC² and Council Directive 82/471/EEC³.
- (2) Article 10(5) of Regulation (EC) No 1831/2003 imposes an obligation on the Commission to adopt a Regulation withdrawing from the market feed additives for which no notification referred to in Article 10(1)(a) of that Regulation was supplied within a specified period. The same obligation applies to feed additives for which no applications in accordance with Article 10(2) and (7) of Regulation (EC) No 1831/2003 were submitted before the deadline provided for in those provisions, or for which an application was submitted but subsequently withdrawn.
- (3) Therefore, such feed additives should be withdrawn from the market. As Article 10(5) of Regulation (EC) No 1831/2003 does not differentiate between authorisations issued with a time limit and authorisations without a time limit, for clarity reasons it is appropriate to provide for the withdrawal from the market of feed additives whose limited authorisation periods pursuant to Directive 70/524/EEC have already expired.
- (4) In the case of feed additives for which applications have been submitted only for certain animal species or categories of animals, or applications have been withdrawn only for certain animal species or categories of animals, the withdrawal from the market should only concern the animal species and categories of animals for which no application has been submitted or the application has been withdrawn.

¹ OJ L 268, 18.10.2003, p. 29.

² Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

³ Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition (OJ L 213, 21.7.1982, p. 8).

- (5) As a consequence of the withdrawal from the market of the feed additives, it is appropriate to repeal the provisions authorising them, where such provisions are still in force. Consequently, Commission Regulations (EC) No 2439/1999⁴ and (EC) No 358/2005⁵ should be amended accordingly.
- (6) As regards feed additives whose authorisation did not expire until the date of entry into force of this Regulation, it is appropriate to allow a transitional period for interested parties, within which existing stocks of the additives concerned, premixtures, feed materials and compound feed which have been produced with those additives may be used up, taking account of the shelf-life of certain feed containing the additives in question.
- (7) The withdrawal from the market of the products listed in Annex I does not prevent them from being authorised or subject to a measure concerning their status in accordance with Regulation (EC) No 1831/2003.
- (8) For several substances, micro-organisms or preparations (referred to as “products”), there is uncertainty whether they are feed additives within the scope of Regulation (EC) No 1831/2003. This uncertainty may result from the inclusion of certain products both in the Register of feed additives referred to in Article 17 of Regulation (EC) No 1831/2003 and in the Catalogue of feed materials established in accordance with Article 24 of Regulation (EC) No 767/2009 of the European Parliament and of the Council⁶. The uncertainty may also derive from various doubts or questions expressed by national competent authorities responsible for official controls or by economic operators concerning the classification of certain products, taking into account in particular the guidelines established by Commission Recommendation 2011/25/EU⁷.
- (9) Such uncertainty about the status of certain products with regard to feed additives within the scope of Regulation (EC) No 1831/2003 may jeopardise the marketing of feed products throughout the Union, since the distinction between feed additives and other feed products has implications for the conditions of their placing on the market, depending on the relevant applicable legislation.
- (10) In order to allay the uncertainty regarding the status as feed additives of certain products, it is appropriate to adopt relevant measures under Regulation (EC) No 1831/2003, clarifying that status. Such measures would bring consistency in the treatment of the products concerned and would facilitate the work of the national competent authorities responsible for official controls, while helping the interested economic operators to act in a framework providing for an appropriate level of legal certainty.

⁴ Commission Regulation (EC) No 2439/1999 of 17 November 1999 on the conditions for the authorisation of additives belonging to the group “binders, anti-caking agents and coagulants” in feedingstuffs (OJ L 297, 18.11.1999, p. 8).

⁵ Commission Regulation (EC) No 358/2005 of 2 March 2005 concerning the authorisation without a time limit of certain additives and the authorisation of new uses of additives already authorised in feedingstuffs (OJ L 57, 3.3.2005, p. 3).

⁶ Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC (OJ L 229, 1.9.2009, p. 1).

⁷ Commission Recommendation 2011/25/EU of 14 January 2011 establishing guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products (OJ L 11, 15.1.2011, p. 75).

- (11) To determine whether products are feed additives within the scope of Regulation (EC) No 1831/2003, it is appropriate to refer to the guidelines for the distinction between feed additives, feed materials and other products, established by Recommendation 2011/25/EU. In particular, those guidelines provide for several criteria to be simultaneously considered in a case-by-case evaluation in order to create a profile of each specific product, taking into account all its characteristics. Useful criteria for the differentiation between feed additives and feed materials include the production and processing method, the chemical definition and the level of standardisation or purification, the safety conditions and mode of use, the functionality of the product concerned. In addition, for the sake of consistency, products with similar properties should be classified by analogy.
- (12) The products sodium citrates, potassium citrates, sorbitol, mannitol and calcium hydroxide are included in the Register of feed additives as existing products for which no applications in accordance with Article 10(2) of Regulation (EC) No 1831/2003 were submitted before the deadline prescribed by that provision. They have also been included in the Catalogue of feed materials by Commission Regulation (EU) No 575/2011⁸. However, a re-examination of the profile of those products with regard to the criteria proposed in Recommendation 2011/25/EU led to the conclusion that they should be considered as feed additives within the scope of Regulation (EC) No 1831/2003. In particular, they are defined by their specific functions referred to in the Register of feed additives and their feed additives status allows improved scope for an effective management thereof in terms of safety and mode of use. In addition, account is taken of their classification as additives for use in food.
- (13) The feed additives status of the products sodium citrates, potassium citrates, sorbitol, mannitol and calcium hydroxide makes it necessary to withdraw them from the market as provided for by Article 10(5) of Regulation (EC) No 1831/2003. However, a longer transitional period should be allowed for the withdrawal from the market of those additives and of feed containing them, in order to take account of the legal uncertainty about their classification, allowing interested parties to submit a new application for authorisation of those feed additives under the procedures set out in Regulation (EC) No 1831/2003.
- (14) Most of the products listed in Annex II are included in the Catalogue of feed materials established by Commission Regulation (EU) No 68/2013⁹. However, they are all, in addition, either listed in the Register of feed additives or have been subject to a withdrawal from the market as feed additives under Article 10(5) of Regulation (EC) No 1831/2003. In order to provide legal certainty concerning the status of those products, their respective profiles were examined in the light of the criteria proposed in Recommendation 2011/25/EU, leading to the conclusion that they should no longer be considered as feed additives within the scope of Regulation (EC) No 1831/2003.
- (15) As regards the labelling of the products listed in Annex II which are still allowed on the market as feed additives, and the labelling of premixtures, feed materials and compound feed containing those products, a transitional period should be provided for to allow feed business operators to adapt. Furthermore, those products should be deleted from the Register of feed additives.

⁸ Commission Regulation (EU) No 575/2011 of 16 June 2011 on the Catalogue of feed materials (OJ L 159, 17.6.2011, p. 25).

⁹ Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials (OJ L 29, 30.1.2013, p. 1).

- (16) The products xylitol, ammonium lactate and ammonium acetate are included in the Catalogue of feed materials established by Regulation (EU) No 68/2013. However, some doubts have been expressed notably by national competent authorities responsible for official controls as to their legal status, which led to an examination of their respective profiles based on the criteria proposed in Recommendation 2011/25/EU. Based on that examination, it has been concluded that those products should be considered as feed additives within the scope of Regulation (EC) No 1831/2003. In particular, the characteristics of xylitol are very similar to those of mannitol and sorbitol, which are considered as feed additives, and the classification of xylitol as a feed additive by analogy would bring consistency in the treatment of those similar products. In addition, account is taken of the classification of xylitol as additive for use in food. As regards ammonium lactate and ammonium acetate, they are chemically well-defined substances that are purified and exerting a specific function defined in Article 5(3) of Regulation (EC) No 1831/2003 and their feed additives status allows improved scope for an effective management thereof in terms of safety and mode of use. Moreover, a classification of ammonium lactate and ammonium acetate as feed additives would bring consistency with other similar products considered as feed additives, such as ammonium propionate or ammonium formate.
- (17) As a result of the classification of xylitol, ammonium lactate and ammonium acetate as feed additives within the scope of Regulation (EC) No 1831/2003, it is appropriate to provide for a transitional period which would allow interested parties to adapt to the new status of those products, including the submission of an application for authorisation, and the further processing thereof, under the procedures set out in Regulation (EC) No 1831/2003.
- (18) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Withdrawal from the market

The feed additives specified in Annex I shall be withdrawn from the market in respect of the animal species or categories of animals as specified in that Annex.

Article 2

Transitional measures for the feed additives to be withdrawn from the market

1. Existing stocks of the feed additives listed in Chapters I.A and I.C of Annex I may continue to be placed on the market and used until [*12 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*].
2. Premixtures produced with the additives referred to in paragraph 1 may continue to be placed on the market and used until [*15 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*].
3. Compound feed and feed materials produced with the additives referred to in paragraph 1 or with the premixtures referred to in paragraph 2 may continue to be placed on the market and used until [*24 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*].

4. By way of derogation from paragraphs 1, 2 and 3, the feed additives sodium citrates, potassium citrates, sorbitol, mannitol and calcium hydroxide listed in Chapter I.A of Annex I, and feed produced with those additives, may continue to be placed on the market and used until [7 years from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication].

Article 3

Amendment to Regulation (EC) No 2439/1999

In the Annex to Regulation (EC) No 2439/1999, entry E 558 on bentonite-montmorillonite is deleted.

Article 4

Amendment to Regulation (EC) No 358/2005

In Annex II to Regulation (EC) No 358/2005, entry E 141 on chlorophyll copper complex is deleted.

Article 5

Products not considered as feed additives within the scope of Regulation (EC) No 1831/2003

1. The substances, micro-organisms or preparations (referred to as “products”) set out in Annex II are not feed additives within the scope of Regulation (EC) No 1831/2003.
2. Products referred to in paragraph 1 which are lawfully on the market and are labelled as feed additives and premixtures before [3 years from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] may continue to be placed on the market until stocks are exhausted. The same applies to feed materials or compound feed which refer to those products in their labelling as feed additives in accordance with Regulation (EC) No 767/2009.

Article 6

Products considered as feed additives within the scope of Regulation (EC) No 1831/2003

1. The substances, micro-organisms or preparations (referred to as “products”) set out in Annex III are feed additives within the scope of Regulation (EC) No 1831/2003.
2. Products referred to in paragraph 1 may continue to be placed on the market and used until [7 years from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication].

Article 7

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN